Amt 3

[beads;], nitrocellulose, nylon; cellulose, polyacrylamide, cross-linked dextran and microcrystalline glass.--

R E M A R K S

The specification and claims are amended herewith in a manner that is believed to place this application in condition for allowance at the time of the next Official Action.

Turning now to the issues raised in the outstanding Official Action, the present amendments to claim 1 correct the informalities noted at page 2 of the Official Action. Similarly, the amendments to pages 5 and 6 of the specification clarify the language objected to by the Examiner at page 2 of the Official Action.

On page 3 of the Official Action, claims 1-3 were rejected under the first paragraph of 35 USC §112, as allegedly being based on a non-enabling disclosure. The basis of that rejection was the allegation that the specification "fails" to teach procedures for making recombinant p26. That rejection is respectfully traversed, for the following reasons.

The rejection is defective as a matter of law because it assumes, without supporting evidence, that those skilled in this art would be unable to make recombinant p26 based on their pre-existing knowledge. Instead, the Official Action merely offers the conclusory allegation that a skilled artisan would not have the requisite reasonable expectation of

success in making recombinant p26, but that allegation lacks the necessary factual underpinning. As stated for example in *In re Dinh-Nguyen et al.*, 181 USPQ 46 (CCPA 1974).

> An assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubts so expressed.

As a factual matter, the contention made in support of the non-enablement rejection is also contradicted by the evidence of record. In particular, the applied PORTER et al. reference 4,806,467, as well as the applied SHEN et al. paper (Enzyme-Linked Immunosorbent Assay for Detection of Equine Infectious Anemia Antibody to Purified P26 Viral Protein), demonstrate that the p26 antigen is a well-known and well-characterized material, for many years. Still further, the applied REIS et al. reference (1996 GenBank Acc. No. U53452) claims to have actually made a recombinant p26, although only the partial sequence is disclosed.

From the above discussion and review of the evidence of record, it is believed to be apparent that those skilled in this art well know how to make the necessary material for practice of the present method. The non-enablement rejection should therefore be withdrawn.

At pages 3-4 of the Official Action, an indefiniteness rejection was applied to claims 1-3 as previously in the case, on the basis of several well-taken formal criticisms of those claims.

In response to that rejection, claims 1-3 are amended herewith as to form, and in a manner that is believed to make the scope of those claims clear. It is accordingly believed that the rejection of claims 1-3 as previously in the case for indefiniteness, should not be applied to the claims as amended.

At pages 5 and 6 of the Official Action, claims 1-3 were rejected under 35 USC §103 as allegedly being unpatentable over PORTER et al. and SHEN et al. in view of PETERSON et al. 5,427,907 and REIS et al. That rejection is also respectfully traversed, for the following reasons.

It is true that PETERSON et al. disclose an EIA assay which is somewhat similar to the claimed assay, but this involves GP-45 instead of recombinant p26. Further, this document does not suggest that p26 could be used in the disclosed assay, because of the likelihood of false positive results. Additionally, the virus is hard to culture.

It is also true that PORTER and SHEN et al., disclose an EIA assay involving p26 core antigen obtained from cultured virus. The problems with these assays are the same as mentioned above. Another drawback is also that it does not involve stable reagents, i.e. the cultured p26 core antigen.

P26 is known as the capsid or core antigen and is the mature protein found in the mature virus capsid. It constitutes 30% of the protein mass from the equine infectious anaemia virus (EIA virus). This group of viruses presents antigenic variation, especially with the envelope proteins as

the gp45 protein used in PETERSON et al. PETERSON et al. proposed the use of synthetic peptides to detect antibodies against a single epitope. Instead we disclose the use of rp26 (recombinant protein p26) that is produced in Escherichia coli or other expression system, that can be used in higher concentrations (0.01-1g) to detect the antibodies 7 days after experimental infection. The antibodies were detected in serum dilutions up to 1:256 (see Fig.2).

The use of recombinant p26 antigen for the diagnosis of EIAV has the advantages not only that the protein is produced in high concentration and it is possible to resolve the false-positive results, but also that the high concentration of purified recombinant proteins means that high concentrations of purified antigen can be bound to the solid phase. The results of Fig. 3 show that some false negative sera with IDGA (agar gel immunodiffusion reaction U.S. 3,929,982; COGGINS) were surprisingly resolved with the recombinant antigen.

Thus there is a significant unexpected result of the present new invention involving stable recombinant p26 in an EIA assay. This assay is also faster, more easily and quickly performed compared to the above mentioned assays. It also overcomes other disadvantages of the other EIA assays mentioned above. Further, the recombinant p26 may be produced in sufficient amounts at a low cost.

Possibly, a person skilled in the art might think to try an assay similar to ours, but the advantages described

above could not be predicted. Accordingly, it cannot be deemed obvious for a person skilled in the art that using the recombinant p26 in an EIA assay according to the present claims would give the unexpected effect which we have disclosed.

Consequently, it is believed to be apparent that the proposed obviousness rejection of previous claims 1-3 must also be withdrawn.

In view of the present amendment and the foregoing remarks, therefore, it is believed that this application is now in condition for allowance, with claims 1-3, as amended. Allowance and passage to issue on that basis are accordingly respectfully requested.

Respectfully submitted,

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